Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

Re-evaluation Note REV2015-14

Special Review Decision: Paraquat

(publié aussi en français)

23 December 2015

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0630 (print)
1925-0649 (online)

Catalogue number: H113-5/2015-14E (print version)
H113-5/2015-14E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2015

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Table of Contents

Special Review Decision 1
Other Information 1
Appendix I Comments and Responses 3
1.0 Scope of the special review of paraquat 3
1.1 Comment on the concentration of paraquat in Gramoxone Liquid Herbicide 3
1.2 Comment on the environmental risk assessment 3
1.3 Comment on the number of incident reports considered for the special review 4
1.4 Comment on the human health risk assessment 4
2.0 Proposed Mitigation Measures 5
2.1 Comment on designation of the end-use product as 'Restricted Class' 5
2.2 Comment on additional PPE for workers to reduce the potential dermal and inhalation exposure 7
2.3 Comment on additional label statements (hazard warnings, toxicological information related to the seriousness of health effects, and revised first aid and treatment advice) .. 7
2.4 Comment on reducing the concentration of paraquat in the end-use product to lower the potential for accidental ingestion of a lethal dose of paraquat and the proposed implementation timeline 7
2.5 Comment on modified packaging including a built-in capacity for measuring the required volume of the product 8
2.6 Comment on proposed prohibition of tank mixing with other pest control products 9
2.7 Comment on proposal to develop a stewardship/outreach program for users and vendors 9
2.8 Comment on the proposed decision for paraquat 10
3.0 Implementation timelines 11
3.1 Comments on the proposed implementation timeline for label amendments 11
3.2 Comments on the proposed implementation timeline for reduced concentration of paraquat in the end-use product and modified packaging 11
Appendix II Risk Mitigation Measures and Implementation Timelines for Products Containing Paraquat 13

Special Review Decision

Pursuant to subsection 17(2) of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA) conducted a special review of pest control products containing paraquat based on decisions taken by the European Union in 2007 and by Sweden in 1983. The PMRA evaluated the aspects of concern that prompted the special review in accordance with subsection 18(4) of the *Pest Control Products Act*. The proposed special review decision was published for consultation in the Re-evaluation Note REV2015-10, *Special Review of Paraquat: Proposed Decision for Consultation*, and it outlines the Agency's proposed decision and the reasons for it.

Comments received during the consultation process were taken into consideration in making this special review decision. Appendix I summarizes the comments received during the consultation period and provides the PMRA's response to these comments. The received comments did not change the proposed regulatory decision as described in REV2015-10. Consequently, the PMRA, under the authority of the *Pest Control Products Act*, is amending the current registration of pest control products containing paraquat in Canada with the additional risk reduction measures and implementation timelines outlined in Appendix II.

Regulatory Directive DIR2014-01, *Approach to Special Reviews*, presents the details of the PMRA's special review approach.

Other Information

Any person may file a notice of objection[1] regarding this decision on paraquat within 60 days from the date of publication of this special review decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website, Request a Reconsideration of Decision, or contact the PMRA's Pest Management Information Service.

[1] As per subsection 35(1) of the Pest Control Products Act.

Appendix I Comments and Responses

The PMRA received comments from stakeholders in response to Re-evaluation Note REV2015-10, *Special Review of Paraquat: Proposed Decision for Consultation*. The PMRA consolidated and summarized the comments related to this special review and provides responses below.

1.0 Scope of the special review of paraquat

1.1 Comment on the concentration of paraquat in Gramoxone Liquid Herbicide

The registered concentration of paraquat in Gramoxone Liquid Herbicide (Registration Number 8661) in Canada is 200 g paraquat *ion*/L (equivalent to 276 g paraquat dichloride/L). The PMRA calculations appear to have been completed under the incorrect assumption that the label guarantee for paraquat in Gramoxone Liquid Herbicide is 200 g paraquat *dichloride*/L. The maximum labelled application rate for Gramoxone Liquid Herbicide in Canada is 5.5 L/ha (equivalent to 1.1 kg paraquat ion/ha when calculated on a 200 g paraquat ion/L basis). A submission was made under Category C submission program to improve clarity around the product guarantee on the registered Gramoxone Liquid Herbicide label.

PMRA Response
The PMRA acknowledges the comment on the label guarantee for the currently registered Gramoxone Liquid Herbicide. However, the updated application rate does not affect the regulatory decision on paraquat. Clarity around the paraquat guarantee (if needed) will be addressed upon completion of the Category C submission.

1.2 Comment on the environmental risk assessment

The calculated risk quotients for birds and mammals exceed the level of concern for acute and chronic exposures. The PMRA dismisses this on the bases that "fields exposed to paraquat are not expected to be a significant food source for birds" and small mammals. Little justification is provided for this assertion and indeed it would be hard to defend given the wide variety of crops on which paraquat may be used. The hazard label statements contemplated in REV2015-10, "Toxic to birds" and "Toxic to small wild mammals", are unlikely to meaningfully reduce this risk.

PMRA Response
As part of the special review, the PMRA assessed the reproductive risk to birds and risk to mammals based on exposure scenarios that assumed a direct application of paraquat at the maximum seasonal application rate and assuming that the diet is comprised entirely of a particular dietary item (for example grains or fruits). The calculated risk quotients (RQs) indicate that the reproductive risk to birds and risks to small mammals are of concern for the modelled scenarios. However, in determining the risk posed by paraquat to non-target species, the PMRA took into consideration the results of the risk assessment, the use information (timing and method of application), and environmental fate of paraquat. Taking into consideration the timing of application to some crops, i.e. pre-emergent (field crops, vegetables, potato, asparagus), pre-seeding (alfalfa and birdsfoot trefoil), post-cutting (alfalfa), or early growth stage applications

(birdsfoot trefoil), the paraquat-treated fields are not expected to be a significant food source for birds. For established crops (i.e. fruit crops, strawberries, vegetables, and nursery crops), the deposition of paraquat residues on the crop is expected to be minimal given the requirement of use of groundboom sprayers with drift-reducing shields. It is also highly unlikely that the diet will comprise entirely of a single dietary item. Furthermore, environmental fate data indicate strong adsorption to soil and biological materials resulting in the reduced bioavailability of paraquat residues. Based on the above, the PMRA concluded that the potential reproductive risk to birds and the potential risk to mammals under the current conditions of use will be lower than the estimated risk and is not expected to be a concern.

1.3 Comment on the number of incident reports considered for the special review

There is a discrepancy between the number of Canadian incident reports cited by the PMRA in REV2015-10 and those captured in the publically available incident report database. Records listed in the database occurring between 2007 and 2015 are limited to six Canadian human incidents and one environment.

PMRA Response
The publically available pesticide incident reporting database contains incident reports submitted to the PMRA after April 2007. All available information was considered as part of the special review, including knowledge of incidents that occurred prior to 2007.

1.4 Comment on the human health risk assessment

The only human health risks considered in the special review of paraquat are potential acute effects as a result of accidental occupational exposure. In general, the REV2015-04 makes no mention of the section 19(2)(b) requirements for special review. A more comprehensive evaluation of human health risks that meets the section 19(2)(b) is requested, including a consideration of chronic risks to agricultural workers from routine exposure to paraquat.

PMRA Response
When a special review is initiated under subsection 17(2) of the *Pest Control Products Act*, the PMRA carries out an analysis of the available information from the OECD member countries (where the pesticide is prohibited) to identify the aspect(s) of concern related to the prohibition. For paraquat, the PMRA reviewed the available information from the European Union and Sweden, including information pertaining to the potential chronic risk to agricultural workers. The aspects of concern related to human health that prompted the special review were identified as:

1) potential risk of health effects as a result of accidental exposure in occupational settings, and
2) potential occupational risk to workers applying paraquat using backpack equipment.

The aspects of concern were then evaluated as required under subsection 18(4) of the *Pest Control Products Act* based on the available relevant information including information from the European Union and Sweden. In evaluating the aspects of concern related to human health that prompted the special review, the PMRA applied a science-based approach in accordance with section 19(2)(a) and considered available information that was relevant to the identified aspects

of concern for this special review in accordance with section 19(2)(b). It should be noted that only commercial-class products containing paraquat are registered in Canada, therefore, residential uses of paraquat are not expected. The potential risk to human health resulting from dietary exposure was not identified as an aspect of concern for this special review. Consequently, non-occupational exposure and risks were not assessed for this special review.

To mitigate the risk of accidental exposure (aspect of concern), the PMRA determined that additional measures are required including additional Personal Protective Equipment (PPE).

In addition to the assessment of accidental exposure and acute effects of paraquat, as part of the special review, the PMRA considered the potential occupational risk to workers mixing, loading and applying paraquat using backpack equipment. The routes of exposure included both dermal and inhalation routes, and for the assessment, the PMRA considered the available information including the toxicological profile of paraquat (including subchronic and chronic animal studies at low exposure doses), exposure data for workers using backpack equipment, and the level of PPE that the PMRA considered necessary to minimize the risk of accidental exposure (see Appendix II). The PMRA determined that with the required additional PPE (i.e. chemical-resistant coveralls over a long-sleeved shirt, chemical resistant gloves, protective eyewear, socks and chemical resistant footwear, and either a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides for all workers during mixing, loading, application, clean-up and repair), the level of occupational exposure is expected to be minimal for all exposure scenarios as long as the revised label is adhered to, which includes the additional risk mitigation measures. On this basis, the potential occupational risk to workers routinely applying paraquat using backpack equipment was not considered to be of concern. It should be noted that additional PPE described above is required for all workers, including those applying paraquat using groundboom equipment. Consequently, the potential occupational risk resulting from routine applications using groundboom equipment is also not expected to be of concern.

2.0 Proposed Mitigation Measures

2.1 Comment on designation of the end-use product as 'Restricted Class'

Several comments indicated that there is a general recognition of the inherent toxicity of paraquat and the need for those using this product to be trained on best practices for handling such pesticide. One comment indicated that there is little opposition from growers to its designation as a "Restricted Class", although small-scale vegetable producers may be impacted. Designation of paraquat product as "Restricted Class" will require that all users of the product will be trained on the safe use of paraquat-containing products in accordance with the National Standard for Pesticide Education, Training and Certification in Canada. The classification will further support the consistent communication and awareness of the principles behind the safe use of paraquat-containing products. However, it should be noted that there are discrepancies between provinces/territories in terms of certification and licensing requirements.

A further dialogue between the PMRA, the registrant and the Federal-Territorial-Provincial (FPT) Working Group responsible for Pesticide Education, Training and Certification (WGPETC) is suggested to consider how the proposed mitigation measures can be incorporated into pesticide certification programs across the country, as well as identifying additional outreach activities in support of the proposed measures.

One comment proposed a revision to the proposed statement regarding the use of the product by "individuals holding and appropriate pesticide applicator certificate or licence recognised by the provincial/territorial pesticide regulatory body" by removing the word "licence" to increase the clarity of the requirement.

One comment indicated that it is not clear on how the designation of the end use product as Restricted Class would reduce risks in a meaningful way. Gramoxone is already labelled "for use only by farmers and pest control operators" and permits issued under provincial pesticide regiments commonly require these pesticide applicators to be licensed to use products with the toxicological profile of paraquat. In Ontario, for example, Gramoxone is listed as a Class 3 pesticide and farmers and pest control operators must be licensed to use pesticides in this class. Federal designation as Restricted Class is unlikely to result in any change to the way this product is used in Ontario.

PMRA Response

The PMRA and provincial and territorial pesticide regulatory agencies/departments recognize that education of those individuals who sell and apply pesticides is a key element in promoting the responsible use of pest control products to protect human health and the environment. By implementation of the Standard for Pesticide Education, Training and Certification in Canada (National Standard), provinces and territories can achieve uniformity for pesticide education, training and certification programs in Canada while still maintaining provincial, territorial and regional flexibility.

The National Standard has resulted in more uniform pesticide education across Canada. Certification programs based on the National Standard incorporate the best possible information on proper pest control product use including updated information on application technology. Implementation of the concepts of the National Standard helps applicators and vendors to use and handle pesticides responsibly and to reduce risk.

The proposed statement related to "Restricted Class" included in REV2015-10 has been developed in collaboration with the FPT Committee on Pesticides and Pest Management, which includes the members of the education subcommittee.

Classification of the paraquat product as a "Restricted Class" on its own is not anticipated to address all identified risks, but is considered as one of elements of the overall strategy to reduce the potential risks.

2.2 Comment on additional PPE for workers to reduce the potential dermal and inhalation exposure

There is no objection to the proposed additional PPE for workers to reduce the potential for dermal and inhalation exposure. However, chemical-resistant coveralls, similar to the respirator requirement, are not needed for applicators using groundboom equipment in an enclosed cab.

PMRA Response
Consistent with PMRA practice, PPE requirements for applicators using groundboom equipment have been revised to accommodate the use of groundboom equipment with a closed cab (see Appendix II for details).

2.3 Comment on additional label statements (hazard warnings, toxicological information related to the seriousness of health effects, and revised first aid and treatment advice)

One comment received indicate that the REV2015-10 offers no explanation of why these new label requirements might be expected to effectively reduce risks, given the evidence that dangerous practices continue despite label warnings and PPE directions.

Other comments received supported the continued clear and complete communication in respect of hazard warnings and first aid and treatment advice to assure prompt and appropriate treatment.

PMRA Response
Based on the available information, the PMRA concluded that additional mitigation measures are necessary to reduce the risk of exposure in occupational settings, including the risk of accidental ingestion due to transferring the product to a beverage container. The purpose of the additional hazard warnings (including information related to oral hazard), and first aid and treatment advice are to provide both users and medical professionals with the most up-to-date information regarding hazards and treatment. Additional PPE is expected to minimize the potential for exposure in occupational settings. No single mitigation measure on its own is anticipated to address all identified risks; rather, they are to be used in combination.

2.4 Comment on reducing the concentration of paraquat in the end-use product to lower the potential for accidental ingestion of a lethal dose of paraquat and the proposed implementation timeline

One comment indicated that of the six incident reports in Canada in the period of 2007 to 2015, there were two oral ingestion incidents both of which resulted in a fatal outcome. The detailed reports of the Canadian oral ingestion incidents suggest that one of the incidents involved a product not registered or legally sold in Canada while the other involved illegal decanting of the product. It is unclear from the details provided in the incident reports whether both of these incidents were, in fact, accidental. The reduced concentration of paraquat in the end-use product may change the clinical progression for an individual but there is also the potential that this does not result in survival.

The proposed mitigation measure is not expected to significantly reduce the identified risk in occupational settings or further reduce the low frequency illegal practice of decanting to inappropriate containers. If implemented, this mitigation measure is expected to significantly affect the agricultural sector in terms of cost (storage, transport, number of containers, carbon footprint, disposal, and the availability of product) and the potential for exposure (higher volumes of product handled, higher potential for accidental splashes to the skin and eyes).

PMRA Response

Accidental ingestion of a single swallow of the currently registered Gramoxone product (200 g paraquat per litre) can be fatal. The PMRA considered the received comments together with information from other countries (including Japan) where the concentration of paraquat in the end-use product has been reduced. The available information showed that the concentration of paraquat in the end-use product greatly impacts the survivability following an accidental ingestion of paraquat. Consequently, the PMRA concluded that to reduce the potential risk of life-threatening or fatal outcomes from an accidental swallow, a reduction in the concentration of paraquat in the Gramoxone product is required along with other risk reduction measures. In addition, the reduced concentration would also reduce the potential risks of serious skin or eye effects from accidental splashes. It should be noted that the application rate remains the same as on the current label. Therefore, the level of potential exposure to paraquat for workers mixing, loading and applying the end-use product containing this active ingredient will not increase.

2.5 Comment on modified packaging including a built-in capacity for measuring the required volume of the product

Some comments received indicated support for the proposed modified packaging. One comment provided information on modified packaging using visiline containers. The use of visiline containers is proposed as part of an overall stewardship strategy to reduce potential occupational exposure to paraquat. A visiline container is a volume window with graduated markings that allow the user to observe and record how much material has been transferred. This measure could be augmented with the inclusion of a product lid sticker that includes a "*do not pour*" pictogram illustrating that the product should not be transferred into any secondary (i.e. smaller) container. Typically, growers will transfer the entire content of a 5 L jug into a spray tank when applying paraquat to large areas. However, visiline strips on 5 L plastic containers are an effective way for growers and other users to measure lower amounts of product into the spray tank or backpack sprayers for smaller areas that require treatment, without the need for a secondary measuring container.

Another comment acknowledged that the modified packaging to include a built-in capacity for measuring the required amount of the product may reduce risk of acute exposure in specific scenarios.

PMRA Response

The modified packaging, that would allow the user to observe and record how much material has been transferred, is expected to reduce the potential for accidental ingestion and is required to be implemented as of 1 April 2017. As with the other proposed mitigation measures, no single mitigation measure on its own is anticipated to address all identified risks, rather, they are to be used in combination.

2.6 Comment on proposed prohibition of tank mixing with other pest control products

There is no evidence from the incident reports on paraquat in Canada that suggests that the act of tank mixing was related to accidental ingestion cases. It is also not clear how this risk reduction measure will affect the potential risk.

The availability of the tank mixes of paraquat with other herbicides plays an important role in achieving a broader spectrum of weed control, controlling resistant biotypes in horticultural crops, and improving sustainability by reducing the consumption of water and fuel, and the equipment requirements.

The potential risk presented by transfer of product into a container for compatibility testing can be mitigated through communication that on-farm compatibility tests are unnecessary in Canada. It is proposed that clear label language stating that compatibility has been tested for labelled tank mix combinations be added to the product label. Growers could also be directed to contact the registrant directly for further compatibility information. Such label indications will be effective in communicating best practices and reducing potential risk associated with tank mixing. Furthermore, a product lid sticker that includes a "*do not pour*" pictogram illustrating that the product should not be transferred into any secondary (i.e. smaller) container could also be considered.

PMRA Response

The PMRA considered the additional risk reduction measure proposed by the registrant (product lid sticker with a "*DO NOT pour*" pictogram illustrating that the product should not be transferred into any secondary container and additional label statements regarding the compatibility with labelled tank mix partners, as well as instructing the users to contact the registrant for additional compatibility information) and use information. Based on the analysis of new information, the PMRA concluded that the proposed risk reduction measures described above combined with the stewardship program and the required additional label amendments provide a viable alternative to the prohibition of tank mixing of paraquat product. Consequently, the PMRA determined that tank mixing of the Gramoxone product with labelled tank mix partners can be allowed provided that other risk reduction measures (including a product lid sticker with a "*DO NOT pour*" pictogram) and additional label amendments are implemented.

2.7 Comment on proposal to develop a stewardship/outreach program for users and vendors

The proposal to develop a stewardship/outreach program for users and vendors is in general supported by the commentators. An outreach program is proposed to be initiated prior to the 2010 application season with the following actions:

- The supply chain will be informed of the PMRA-mandated changes to the product label and provided with additional stewardship materials to be transferred to customers during the sale of a paraquat-containing product.
- Customer-facing staff will be trained to ensure that the new information is shared with retailers.

- The Syngenta Product Emergency Response (PER) System will be updated to reflect the change in first aid and medical care. The Syngenta PER System is available (in English and French) to the public through 1-800-F-YOUNEED, as indicated on all Syngenta product labels, packaging, and Safety Data Sheets, and provides the caller with medical and veterinary support on a 24/7 basis.

A further dialogue between the PMRA, the registrant and the Federal-Territorial-Provincial Working Group responsible for Pesticide Education, Training and Certification (WGPETC) is suggested to consider how the proposed mitigation measures can be incorporated into pesticide certification programs across the country, as well as identifying additional outreach activities in support of the proposed measures.

PMRA's Response

The PMRA supports the proposed actions and will collaborate with the stakeholders on developing a stewardship/outreach program. A registrant-sponsored product stewardship program will play an important role in managing risks. It will also emphasize and promote the importance of adhering to product label requirements and reduce risks by raising awareness of the Gramoxone Liquid Herbicide hazards, prevention of accidental exposure, recognition of symptoms of pesticide poisoning, and, what to do should a poisoning occur. The stewardship program must be developed and implemented by the registrant within the specified timelines (see Appendix II for details) and must include measures to:

- Inform the vendors and users of the required new mitigation measures and, emphasize and promote the importance of adhering to the product label requirements.
- Reduce the risk of accidental exposure by raising awareness of the Gramoxone Liquid Herbicide hazards, prevention of accidental exposure, recognition of symptoms of pesticide poisoning, and, what to do should a poisoning occur.

5.3 Comments on the proposed decision for paraquat

The proposed continued registration of products containing paraquat with the revised conditions of use is supported by some commentators. One commentator is of the opinion that the available information indicates that paraquat may pose unacceptable risks to both human health and the environment, based on available information. Therefore, in keeping with the precautionary principle, as required by the *Pest Control Products Act*, the PMRA should cancel the registration of paraquat and pest control products containing this active ingredient.

PMRA's Response

The PMRA followed a risk-based scientific approach to assess the aspects of concern identified for the special review of paraquat. Based on this assessment, additional risk reduction measures are required to minimize the potential human health and environmental risks. Consequently the PMRA is amending the current registration of Gramoxone Liquid Herbicide with additional risk mitigation measures and timelines outlined in Appendix II, to further protect human health and the environment.

3.0 Implementation timelines

3.1 Comments on the proposed implementation timeline for label amendments

One comment indicated that the implementation of the required label amendments within the proposed timeline is not feasible in time for the 2016 application season considering the time needed to finalize the Special Review decision and approve the revised label changes. A more realistic timeline for finalization of label amendments is prior to the 2017 field season.

PMRA Response
The implementation of the required label amendments in time for the 2016 application season is necessary to minimize the potential for exposure in occupational settings and to increase the awareness of how to prevent accidental exposure.

3.2 Comments on the proposed implementation timeline for reduced concentration of paraquat in the end-use product and modified packaging

The proposed implementation date is not considered feasible considering the information required to support new formulation (product development, generation of the required product-specific studies), the registration process, as well as to address packaging, labelling and supply chain issues. If implemented as proposed, this requirement from the PMRA may result in a lack of access to product on the market as it will not be possible to bring a concentration-reduced product to market within the timeline the PMRA have proposed (i.e. by 1 April 2017).

PMRA Response
The implementation of a reduced concentration of paraquat in the end-use product and a modified packaging is required to further protect human health. The required implementation timeline for the amended Gramoxone product (reduced concentration of paraquat and modified packaging) by the registrant is April 1, 2017. On this basis, the last date of sale of the Gramoxone product, with the current concentration and packaging, by the Registrant is 31 March 2017.

Appendix II Risk Mitigation Measures and Implementation Timelines for Products Containing Paraquat.

The following mitigation measures are required to minimize the potential risks to human health and the environment:

1) The end-use product, Gramoxone Liquid Herbicide, is to be designated as a Restricted Class based on the toxicity profile of paraquat and the potential for accidental exposure. The nature of restriction: "This product is only to be used by individuals holding an appropriate pesticide applicator certificate or licence recognized by the provincial/territorial pesticide regulatory agency where the pesticide application is to occur."

2) Label amendments with additional PPE, hazard warning and treatment advice

    a. Additional PPE:
        - During mixing/loading, cleanup and repair, workers must wear chemical-resistant coveralls over a long-sleeved shirt and long pants, socks and chemical-resistant footwear, chemical-resistant gloves, protective eyewear and either a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides.
        - Applicators using groundboom equipment with:
            i. a closed cab must wear cotton coveralls over a long-sleeved shirt, long pants, shoes plus socks. Chemical-resistant coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, protective eyewear, and either a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides must be worn by applicators when leaving the closed cab for calibration, repair or cleanup. The closed cab must provide both a physical barrier and respiratory protection (i.e. dust/mist filtering and/or vapour/gas purification system). The closed cab must also have a chemical-resistant barrier that totally surrounds the occupant and prevents contact with pesticides outside the cab.
            ii. an open cab must wear chemical-resistant coveralls over a long-sleeved shirt and long pants, socks and chemical-resistant footwear, chemical-resistant gloves, protective eyewear and either a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides.
        - Applicators using backpack sprayers for spot treatment must wear chemical-resistant coveralls over a long-sleeved shirt and long pants, socks and chemical-resistant footwear, chemical-resistant gloves, protective eyewear and either a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides.

b. Additional hazard warnings regarding acute oral, dermal, and eye hazard, toxicological information, revised first aid statements, and additional precautionary statements and storage requirement.

c. Additional label updates related to the use directions for backpack (indicating the use of backpack sprayer only for spot treatment for filberts and hazelnuts) and groundboom (specifying lowboom sprayers for field crops) equipment, respirator use and re-entry instructions, as well as standard environmental label statements (related to paraquat toxicity and measures to minimize the potential for a runoff event).

3) Prohibition of the tank mixing of Gramoxone Liquid Herbicide with pest control products other than those listed on the Gramoxone product label with additional mitigation measures including a lid sticker with a "DO NOT pour" pictogram on the product as well as label statements regarding the compatibility with labelled tank mix partners.

4) Reduced concentration of paraquat in the end-use product to lower the potential for both accidental ingestion of a lethal dose and serious skin or eye effects from accidental splashes.

5) Modified packaging with a built-in capacity to measure the required volume of the product.

6) A stewardship program that includes measures to:
   a. Inform the vendors and users of the required new mitigation measures and emphasize and promote the importance of adhering to the product label requirements.
   b. Reduce the risk of accidental exposure by raising awareness of the Gramoxone Liquid Herbicide hazards, prevention of accidental exposure, recognition of symptoms of pesticide poisoning, and, what to do should a poisoning occur.

   The stewardship program must be phased-in as follows:
   - Phase 1 for the 2016 Growing season: The registrant is required to provide distributors and vendors with information to be distributed to users regarding the new risk reduction measures, health hazards, measures to prevent accidental exposure.
   - Phase 2 for the 2017 Growing season: Development and implementation of a training program in time for 2017 growing season.

The required mitigation measures and label updates are required according to the following timelines:

1 April 2016
• Label amendments and updates • Prohibition of non-labelled tank mix partners • Restricted Classification • Phase 1 of the Stewardship program
1 April 2017
• Reduced concentration of paraquat in the end-use product • Modified packaging with built-in capacity to measure the required volume of product • Phase 2 of the Stewardship program

Based on the above implementation timelines for the required risk mitigation measures, the last date of sale of the Gramoxone product, with the current concentration and packaging, by the Registrant and Retail is 31 March 2017 and 30 September 2017, respectively. The registration of the Gramoxone product, with the current concentration and packaging, will expire on 31 December 2018.